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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,767	05/04/2001	Kun Chen	301505.2003-001	6656
207	7590 01/10/2006		EXAMINER	
WEINGARTEN, SCHURGIN, GAGNEBIN & LEBOVICI LLP			HORWAT, JENNIFER A	
	ΓEN POST OFFICE SQUARE BOSTON, MA 02109		ART UNIT	PAPER NUMBER
,			3737	

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	A	A line and/o				
	Application No.	Applicant(s)				
065 4 4 4 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	09/848,767	CHEN ET AL.				
Office Action Summary	Examiner	Art Unit				
	Jennifer Horwat	3737				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
,	Responsive to communication(s) filed on <u>04 May 2001</u> .					
·—						
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
<ul> <li>4) Claim(s) 1-40 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5) Claim(s) is/are allowed.</li> </ul>						
6)⊠ Claim(s) <u>1-40</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9) ☐ The specification is objected to by the Examine 10) ☑ The drawing(s) filed on 04 May 2001 is/are: a) Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) ☐ The oath or declaration is objected to by the Ex	☑ accepted or b) ☐ objected to liderawing(s) be held in abeyance. Serion is required if the drawing(s) is ob	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).				
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)  1)   Notice of References Cited (PTO-892)  2)   Notice of Draftsperson's Patent Drawing Review (PTO-948)  3)   Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date 10/14/2003.	4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal F 6) Other:					

#### **DETAILED ACTION**

#### Information Disclosure Statement

1. The information disclosure statement filed on 5/5/2000 is in compliance with 37 CFR 1.97-1.98 and all references therein have been considered.

## Claim Objections

2. Claims 22 and 33 are objected to because of the following informalities: In claim 22, the word "function" should be plural and therefore should be replaced with "functions". In claim 33, "alight" should be two words and therefore should be replaced with "a light". Appropriate correction is required.

## Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the first paragraph of 35 U.S.C. 112:
  - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 4. Claims 11 and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There is no mention in the specification as to the method steps or the process for determining the size of a cancerous lesion in the tissue.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 32 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 32, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claim 40, the statement "the light distribution function defines a plurality of light paths having a cross-sectional area, the area being less than diffusion approximation of the area" is unclear. It is not possible to determine what the applicant is claiming.

## Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 8. Claims 1-4, 9, 11-13, 22, 26-29, 34, 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Chernomordik, et al ("Point spread functions of photons in time-resolved transillumination experiments using simple scaling arguments").

Chernomordik discloses a method of imaging in which near-infrared radiation, which is

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approximately between 750 and 3000 nm, is used to image inside an optically turbid slab. The point spread function used is valid at short times and takes into account both scattering and absorption and is valid at short times, "which should be applicable to the analysis of transport through slabs whose thickness is but a few times the inverse of the transport-corrected mean-free path" (pg 1857). A plurality of light distribution functions are used, as the PSF of "any imaging process can be represented as a product of transmission and reception directivity patterns" (page 1858). It is inherent in the disclosure that a light source, a detector, and a data processor connected to the detector would be used in order to obtain the data shown in the figures and that an image is formed from the disclosed image reconstruction algorithms. The imaging allows for the noninvasive detection of tumors, which are embedded in tissue (pg 1857) to allow determination of the size and location of a tumor.

# Claim Rejections - 35 USC § 103

- 9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 10. Claims 6-8, 15, 17-21, 23, 31, 32, 37, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winn, et al ("Distribution of the paths of early-arriving photons traversing a turbid medium"). Chernomordik, as discussed above, discloses a method of imaging an object using a light distribution function, however fails to explicitly

disclose the structural elements used with the light distribution function. Winn also discloses a system and method for optical tomographic imaging in a turbid medium and provides details as to the structural elements used. Winn discloses using a laser to generate the light used, collected with a bundle of optical fibers, and detected by a streak camera detection system (pg 8086), which may be aligned with each other when delta x is set to 0 (pg 8090). The "beam and detectors sweep together horizontally along the tank, and the photon intensity I(t) is recorded at each position x" (pg 8090), which provides relative movement between the object being imaged and the sensor. The detection system is gated by control units (pg 8086). The pulses of the laser light have a duration of 150 fs. It is noted that, "the width of the spatial distribution of paths of early-arriving photons is substantially narrower than that for highly diffused photons" (pg 8085). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Chernomordik with the teachings from the reference by Winn, as the reference discloses an improved system and methods for optical computed tomography to obtain "distribution photon paths in a turbid medium for short times of flight" (pg 8086).

11. Claims 5, 16, 30, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chernomordik in view of Chang, et al (US 5454047). Chernomordik, as discussed above, discloses a method of imaging an object using a light distribution function, however fails to disclose using a light distribution function including a series expansion. Chang discloses an optical method for an image processing function in which a series expansion of a function is used, "the expansion coefficients thus

generated may be used to recreate the image as with a Fourier series approach" (col 1, lines 50-60). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Chernomordik and include a series expansion in the light distribution used by Chernomordik for image processing as "the advantage is that fewer terms are required to effectively recreate an image" (col 1, line 60) thereby decreasing processing time and memory space requirements.

12. Claims 10, 14, 25, 35, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chernomordik in view of Barbour, et al ("Imaging of Subsurface Regions of Random Media by Remote Sensing"). Chernomordik, as discussed above, discloses a method of imaging an object using a light distribution function, however fails to disclose providing a plurality of weighting functions. Barbour also discloses a method for generating optical images of tissue that takes into account both absorption and scattering properties of tissue (pg 192). A weighting function is used to give a weight to each voxel (pg. 196) as well as computing weight functions for all source-detector configurations in order to localize inhomogeneities in 3D space (pg 198), which are displayed as images (figure 4). Barbour also teaches that the problem may employ "a reciprocity theorem of radiation transport theory" (pg. 194). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Chernomordik with the teachings from the reference by Barbour, as it takes into account both absorption and scattering properties of tissue (pg 197) and provides that images in "successively deeper regions" may be obtained using this method as compared with other optical tomography methods.

13. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamashita, et al (US 6240309). Chernomordik, as discussed above, discloses a method of imaging an object using a light distribution function, however fails to disclose using an internal probe to obtain images of the tissue. Yamashita discloses an optical measurement instrument in which a probe is used for optical computed tomography by "effecting tomography on an inner living body with light is image-processed by a computer" (col 12, lines 34-42). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Chernomordik with the teachings from the reference by Yamashita, as using a probe internally as well as

### Conclusion

externally would provide greater flexibility for the system and images could be obtained

for tissue that is well below the skin's surface.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Horwat whose telephone number is (571) 272-2811. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

jah 01/04/2006

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